THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

No. 1:18-cv-502-WJO-JLW

LLOYD BUFFKIN, et al.,	)	
	)	
Plaintiffs,	)	**RESPONSE OF DEFENDANTS TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**
	)	
v.	)	
	)	
ERIK HOOKS, et al.,	)	
	)	
Defendants.	)	

NOW COME Defendants Erik Hooks, Abhay Agarwal, Kenneth Lassiter, Paula Smith, and the North Carolina Department of Public Safety ("the Department") by and through the undersigned counsel, to oppose Plaintiffs' motion for preliminary injunction ("the Motion"), and state the following:

STATEMENT OF THE CASE

On June 15, 2018, Plaintiffs filed their Complaint and a motion to certify this action as a class action. (D.E. 1, 3) On September 12, 2018, Defendants answered the Complaint. (D.E. 25) On September 14, 2018, Plaintiffs filed the instant Motion along with a supporting brief. (D.E. 26, 27)

In the Motion, Plaintiffs seek a preliminary injunction that would mandate that Defendants: 1) implement a universal opt-out screening policy for the hepatitis C virus ("HCV"); 2) cease their reliance on certain contraindications for treatment set forth in the current HCV treatment policy; and 3) provide direct-acting antivirals ("DAAs") to Plaintiffs and other putative class member inmates who have tested positive for HCV in accordance with guidelines issued by the American Association for the Study of Liver Disease and the Infection Diseases Society of America ("AASLD/IDSA Guidance"). (D.E. 26) In opposition to the Motion, Defendants submit the

Affidavit of Anita Wilson, M.D., the Medical Director of Health Services for the Department's Division of Adult Correction and Juvenile Justice, and the exhibits attached thereto.

FACTS

HCV Generally

HCV is a blood borne viral infection transmitted through a variety of methods, including sex, intravenous drug use, and blood transfusions. (D.E. 27-1, ¶ 8) Acute HCV may be asymptomatic or cause mild symptoms such as fatigue, and may spontaneously clear an infected patient's blood. (*Id.* at ¶ 9) The presence of the virus more than six months after infection, however, renders the condition chronic. (*Id.* at ¶ 18) Chronic HCV, too, may produce few discernible symptoms other than fatigue or other mild, non-specific complaints. (D.E. 1-1, ¶ 10; *Id.* at ¶ 9) HCV progresses slowly, with fibrosis (scarring of the liver) and cirrhosis (severe scarring) occurring over a period of years or decades in some patients, while not at all with others. (Wilson Aff. ¶ 9; Ex. C thereto, p. 9; D.E. 27-1, ¶ 9) The rate of progression of fibrosis or cirrhosis varies markedly across individuals on the host as well as environmental and viral factors. (Wilson Aff. ¶ 12; Ex. B thereto, p. 33)

AASLD/IDSA Guidance

The AASLD/IDSA Guidance is an evolving, extensive, detailed, and complex publication and is periodically updated, most recently on May 24, 2018. (Wilson Aff. ¶ 14; Ex. B thereto, p. 4) Although the AASLD/IDSA Guidance advances aspirational and laudable public health statements, it does not create a standard of care for treatment of HCV. (Wilson Aff. ¶¶ 15-16) In fact, the website where the AASLD/IDSA Guidance is published contains a Medical Information Disclaimer providing that "[n]othing contained at HCVguidelines.org is intended to constitute a

specific medical diagnosis, treatment, or recommendation. The information should not be considered complete, nor should it be relied on to suggest a course of treatment for a particular individual." (Wilson Aff. ¶ 16; Ex. B-1 thereto, p.1)

According to the AASLD/IDSA Guidance, accurately assessing fibrosis is "vital because the degree of hepatic fibrosis is one of the most robust prognostic factors used to predict HCV disease progression and clinical outcomes." (Wilson Aff. ¶ 13; Ex. B thereto, p. 32) As an informational and observational resource, the AASLD/IDSA Guidance notes treatment options based on HCV genotype, subtype, previous treatment history, degree of liver fibrosis, and other clinical issues. (Wilson Aff. ¶ 15) Those treatment options include lengthy and detailed information regarding the various possible DAA treatment regimens. (Wilson Aff. ¶ 21; Ex. B thereto, pp. 58-145)

Under the AASLD/IDSA Guidance, a DAA regimen choice should consider patient specific data, including drug interactions and careful pretreatment assessment for comorbidities that may influence treatment response. (Wilson Aff. ¶ 32; Ex. B thereto, pp. 58, 92) Consequently, according to the AASLD/IDSA Guidance, the administration of DAAs varies significantly according to indications, contraindications, dosing and duration, and drug interactions, and rarely involves the simple daily administration of a single pill, to a single patient, at the same time. (Wilson Aff. ¶ 17; Ex. B thereto, pp. 59-144) Importantly, the AASLD/IDSA Guidance explicitly recognizes the appropriateness of prioritization, noting that "in certain settings there remain factors that impact access to medications and the ability to deliver them to patients. In these settings, practitioners may still need to decide which patients should be treated first." (Wilson Aff. ¶ 27; Ex. B thereto, p. 25).

HCV Treatment in State Correctional Settings and the Department's Policy

The correctional environment generates several inherent challenges to treating HCV-infected inmates. The AASLD/IDSA Guidance notes that lack of expertise in HCV treatment is a common clinician-related barrier to treatment, and that lack of trained staff is one of the primary reasons that few inmates in correctional systems receive DAA treatment. (Wilson Aff. ¶ 25; Ex. B thereto, pp. 22, 210) The AASLD/IDSA Guidance also recognizes that costs may be a barrier to providing DAA treatment, both in and outside of correctional settings. (Wilson Aff. ¶ 25; Ex. B thereto, 22, 214)

Indeed, only 16% of prison facilities nationwide test all inmates for HCV upon entry. Similarly, only seventeen states reported offering routine opt-out HCV testing in prison facilities, while only four states report adherence to the Clinical Guidelines of the Federal Bureau of Prisons ("the Federal Guidelines"). (Wilson Aff. ¶ 33; Ex. B, pp. 210-11)

The Department's HCV treatment policy prioritizes DAA treatment based on a patient's individualized medical needs and history. (Wilson Aff. ¶ 34) The policy also provides for all patients (absent contraindications) with a fibrosis score of F2 or higher to be referred to a specialty Hepatology clinic for evaluation and, if warranted, administration of DAAs. (Wilson Aff. ¶ 38)

Argument

Plaintiffs' seek a preliminary injunction pursuant to Rule 65(a) of the Federal Rules of Civil Procedure. (D.E. 26) "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

Plaintiffs' Motion for Preliminary Injunction should be denied for three principal reasons. First, Plaintiffs lack standing to seek the requested relief, both individually and on behalf of the proposed class. Second, the relief requested extends far beyond the Court's authority as provided in the Prison Litigation Reform Act ("PLRA"). Lastly, Plaintiffs fail to meet the rigorous standards required to receive preliminary injunctive relief, namely they have not established that their deliberate indifference claims are likely to succeed on the merits, that the equities weigh in favor of preliminary relief, or that a preliminary injunction is in the public interest.

I. Plaintiffs' Lack Standing to Seek the Requested Relief.

"In order to have standing, a plaintiff must establish, *inter alia*, that he has suffered an injury in fact, that is, an invasion of a legally protected interest which is concrete and particularized, as well as actual or imminent." *Peterson v. National Telecomms. & Info. Admin.*, 478 F.3d 626, 631-32 (4th Cir. 2007) (internal quotation and citation omitted). The movant must demonstrate a "realistic danger of sustaining a direct injury as a result of" the alleged illegal conduct. *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979). "Where no such injury is present, federal courts are without constitutional authority to consider a plaintiff's claims." *Peterson*, 478 F.3d at 632. Plaintiffs cannot meet this standard and, therefore, lack standing to pursue both preliminary injunctive relief to compel Defendants to adopt an opt-out screening procedure for HCV, and to obtain a directive that Defendants cease their reliance on various contraindications when determining whether to administer DAAs.

A. Universal Testing Would Not Affect the Plaintiffs.

In support of their pursuit of an injunction compelling the Department to implement an opt-out HCV screening procedure, and under the false premise that the Department's risk-based

screening is deficient, Plaintiffs rely on the AASLD/IDSA Guidance that suggests universal screening for HCV in circumstances involving particular populations. (D.E. 1, ¶¶ 36-37, 87) Even assuming Plaintiffs' assertion is accurate, they have failed to alleged, and cannot show, that these Plaintiffs have or will sustain any actual injury as a result of the Department's risk-based screening.

An individual named Plaintiff cannot seek relief on behalf of a purported class when the individual is not entitled to such relief. *See Gratz v. Bollinger*, 539 U.S. 244, 289 (2003) ("named plaintiffs who represent a class must allege and show that they personally have been injured"). The named Plaintiffs have each previously been diagnosed with HCV, and have been so diagnosed at varying times. (D.E. 27, pp. 8, 14) The suggested HCV screening protocols of the AASLD/IDSA Guidance benefit only those patients who have not yet been diagnosed with HCV. As such, the implementation of an opt-out screening policy simply does not impact patients who have already been diagnosed with the infection. (Wilson Aff. ¶ 40) Consequently, the implementation of an opt-out screening policy recommended by the AASLD/IDSA Guidance will have no effect on the named Plaintiffs. The named Plaintiffs, therefore, cannot be harmed by the non-implementation of the AASLD/IDSA Guidance's screening recommendations and lack standing to pursue this claim.

B. No Indication that Reliance on Contraindications Has or Will Cause Harm to Plaintiffs.

The Department's HCV treatment policy provides five contraindications to treatment with DAAs, including infractions related to the use of alcohol or drugs, and unstable medical or mental health conditions. (Wilson Aff.; Ex. D thereto p. 5) Plaintiffs contend that the use of all but one of the contraindications lack medical justification and seek to enjoin the Department from using all but that one contraindication. (D.E. 27, p. 15)

Plaintiffs, however, have not alleged that they are being denied HCV treatment based on

any of the five contraindications and cannot show that they have, or will sustain, an actual injury as a result of the Department's use of the contraindications. Instead, Plaintiffs appear to rely on a hypothetical patient – and putative class member – who could be denied DAA treatment based on any of the contraindications listed in the Department's policy. This is insufficient to confer standing on the named Plaintiffs. *See Doe v. Obama*, 631 F.3d 157, 160 (4th Cir. 2011) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 n. 20 (1976)) ("The Supreme Court has made clear that named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent."). Consequently, Plaintiffs lack standing to pursue preliminary injunctive relief mandating that the Department eliminate the use of the challenged contraindications to treatment with DAAs.

II. The PLRA bars Plaintiffs' Overbroad Request for Relief.

The preliminary injunctive relief requested by Plaintiff's is overbroad and exceeds the Court's authority under the PLRA. A court may only grant prospective relief if it finds "that such relief is narrowly drawn, extends no further than necessary to correct the violation of the Federal right, and is the least intrusive means necessary to correct the violation of the Federal right." 18 U.S.C. § 3626(a)(1)(A). The limitations on the intrusiveness of injunctive relief have been acknowledged by the Supreme Court, which held that "[t]he PLRA has restricted courts' authority to issue and enforce prospective relief concerning prison conditions, requiring that such relief be supported by findings and precisely tailored to what is needed to remedy the violation of a federal right." *Miller v. French*, 530 U.S. 327, 347 (2000). The Fourth Circuit Court of Appeals, too, has explicitly recognized that "the fundamental purpose of the PLRA, [] was to remove the federal

district courts from the business of supervising the day-to-day operation of state prisons." *Cagle v. Hutto*, 177 F.3d 253, 257 (4th Cir. 1999).

Here, Plaintiffs seek mandated universal screening for HCV, a rewritten HCV policy that eliminates the use of contraindications by the Department, and the supplanting of an individualized medical assessment in favor of a one-size-fits-all approach to treatment of HCV in the Department's inmate population. On their face, these requests defy the requirements that they be narrowly drawn, extend no further than necessary to correct a violation, and constitute the least intrusive means for doing so.

Here the Plaintiffs' requested relief is not narrowly drawn – they seek uniform application of medical care across a diverse population without due regard to patient-specific factors. For example, Plaintiff's requested relief does not articulate or contemplate a procedure for evaluating an individual patient for the appropriate regimen choice, as is recommended by the AASLD/IDSA Guidance. (Wilson Aff. ¶ 32; Ex. B thereto, pp. 58, 92) The requested relief also extends much further than is necessary to correct the alleged constitutional violation. For example, the requested relief would require the Department to treat all inmates with chronic HCV with DAAs without regard to the progression of the disease and actual risk of harm. Lastly, the requested relief is far from the least intrusive means necessary to correct the supposed constitutional violation. Instead, as explained in more detail below, the requested relief would require a significant overhaul of the Department's capacity and resource allocation and would likely be subject to judicial oversight. The Court should deny Plaintiffs' requested injunctive relief as it violates the PLRA's criteria regarding prospective relief.

III. Plaintiffs Fail to Satisfy the Necessary Standards for a Preliminary Injunction

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). Without pointing to any actual evidence, Plaintiffs summarily conclude that their deliberate indifference claims, on which they premise their request for preliminary injunctive relief, have a high likelihood of success. In making those assertions, however, Plaintiffs overlook the many factors that weigh against the extraordinary remedy they seek.

A. Likelihood of Success on Deliberate Indifference Claim

"[A] prison official violates the Eight Amendment only when two requirements are met." *Farmer v. Brennan*, 511 U.S. 825, 834 (1994). The first requirement is the deprivation of an objectively "sufficiently serious" basic human need and the second is a "sufficiently culpable state of mind" or stated differently, "deliberate indifference" to inmate health or safety. *Id.*

In correctional facilities, medical care constitutes a basic human need, the deprivation of which may, under certain circumstances, form the basis of an Eighth Amendment violation. *Estelle v. Gamble*, 429 U.S. 97, 104 (1976). The Fourth Circuit Court of Appeals has held that that a serious medical need "is one that poses a substantial risk of serious injury to health and safety." *Turner v. Kight*, 121 F. App'x 9, 13 (4th Cir. 2005). Further "serious medical need" as a medical need is defined as "sufficiently serious… to require medical treatment." *Brice v. Virginia Beach Corr. Ctr.*, 58 F.3d 101, 104 (4th Cir. 1995).

The second requirement requires the Court to determine whether Defendant acted with "a sufficiently culpable state of mind." *Short v. Smoot*, 436 F.3d 422, 427 (4th Cir. 2006). This

element of an Eight Amendment violation claim is subjective. *Id.* "Deliberate indifference" has been used to describe a state of mind, and is equated to recklessness, which lies somewhere between negligence and acting with purpose or knowledge of harm. *Farmer*, 511 U.S. at 835-36. "[A] prison official cannot be found liable under the Eighth Amendment … unless the official knows of and disregards an excessive risk to inmate health or safety; the official must both be aware of facts from which the inference could be drawn that a substantial risk of serious harm exists, and he must also draw the inference. *Id.* at 837. "'Deliberate indifference is a very high standard - a showing of mere negligence will not meet it.'" *Parrish ex rel. Lee v. Cleveland*, 372 F.3d 294, 302 (4th Cir. 2004).

The entire premise of Plaintiffs' claim relies upon the concept that any deviation from the AASLD/IDSA Guidance is deliberate indifference. Specifically, Plaintiffs contend that the Department's risk-based screening process, its reliance on certain contraindications, and how, when, and to whom, the Department administers DAAs, constitutes deliberate indifference. This argument is without merit. Plaintiffs cannot show that a risk-based screening approach, as opposed to an opt-out approach, creates an excessive risk of harm. Further, Plaintiffs' suggestion that the contraindications in the Department's HCV Policy are medically unjustified is supported by neither the AASLD/IDSA Guidance nor the Federal Bureau of Prison Guidelines. Lastly, Plaintiffs' characterize the AASLD/IDSA Guidance as a rulebook from which deviation constitutes deliberate indifference. In this regard, Plaintiffs' efforts exaggerate the explicit intention of the Guidance, while contemporaneously ignoring its salient disclaimer provisions.

1. Use of a Risk-Based Screening Does Not Create An Excessive Risk of Harm to Plaintiffs

As noted above, deliberate indifference is established only when a claimant demonstrates

that a prison official was aware of, but nevertheless ignored, an excessive risk to the health or safety of an inmate. *Farmer*, 511 U.S. at 837. In contrast, Plaintiffs here argue that the Department's use of a risk-based screening protocol deviates from those suggested by the AASLD/IDSA Guidance and, therefore, constitutes *de facto* deliberate indifference. That assertion is fundamentally flawed.

In support of their collective proposition, Plaintiffs rely upon numerous cases in their supporting brief, yet not only are these cases from outside the Fourth Circuit, they are factually distinguishable. *See, e.g.*, *Hernandez v. County of Monterey*, 110 F. Supp. 3d 929, 943-44 (N.D. Cal. 2015) (county jail maintained tuberculosis (TB) screening, monitoring, and isolation practices, including using non-medical and untrained staff to perform TB screenings, having no written policy regarding screening, and failing to isolate TB positive inmates, that fell short of CDC Guidelines); *Dawson v. Kendrick*, 527 F. Supp. 1252, 1307-08 (S.D. W. Va. 1981) (calling "grossly deficient" a jail's practices, including, among others, medical screening performed by untrained staff, a total absence of medical supplies or a medical room, and the absence of sick call procedures); *Cody v. Hillard*, 599 F. Supp. 1025, 1035-42, 1062 (D.S.D. 1984) (holding that a prison's provision of medical care was unconstitutional based upon the use of untrained inmates to perform medical and dental services, no established protocol for responding to medical emergencies, and insufficient quantity of medical staff, among others); *Feliciano v. Gonzalez*, 13 F. Supp. 2d 151, 208-210 (D.P.R. 1998) (finding deliberate indifference where prison failed to inquire about inmates' prior medical histories, to treat HIV+ and AIDS patients, and to provide a sick call system or prescribed medications). These cases only demonstrate, however, the irrefutable point that the utter absence of written policies, the complete denial of care for particular

illnesses, and the glaring lack (or insufficient quantity) of qualified health care providers violates the Constitution. The policies and procedures implemented by Defendants – however unsatisfactory to Plaintiffs – far surpass the deficient examples criticized in the cases upon which they rely.

Fundamentally, Defendants have adopted and implemented an evidence-based policy that incorporates concepts from the AASLD/ISDA Guidance, the Federal Guidelines, or both. Plaintiffs here have already been diagnosed with HCV and, therefore, cannot establish that the Department's screening policy has subjected them to a substantial risk of harm let alone actually injured them. Because HCV may be asymptomatic, progresses slowly, and does so at rates that will vary from patient to patient, there is no evidence to suggest that other members of the purported class are subject to an excessive risk of harm by the Department's adherence to a risk-based screening policy. Those inmates who reveal in their medical histories behaviors, events, or clinical symptoms that demonstrate potential exposure to or infection with HCV are tested, monitored, and treated. The fact that the Department does not indiscriminately test every inmate for HCV does not render Defendants deliberately indifferent to any random inmate's serious medical need. Accordingly, this Court should reject that contention and deny the demanded preliminary injunctive relief.

2. Use of Certain Contraindications Does Not Create An Excessive Risk of Harm

Plaintiffs contend that the use of certain contraindications in the Department's HCV Policy is some evidence of deliberate indifference, especially whenever the policy deviates from the AASLD/IDSA Guidance. This contention lacks merit and should be rejected.

In support of their theory that "[p]rison officials cannot deny or delay medically necessary

care for non-medical reasons[,]" Plaintiffs cite two cases: *Estelle v. Gamble*, 429 U.S. 97, 104-05 (1976) and *Hunt v. Sandhir, M.D.*, 295 F. App'x 584, 586 (4th Cir. 2008). (D.E. 27, p, 15) As neither addresses the interplay between claims of deliberate indifference and motions for preliminary injunction, both are unavailing. *Estelle* simply addresses the question of whether that plaintiff's complaint, based on a lack of diagnosis and inadequate treatment of his back injury, was sufficient to state a claim under 42 U.S.C. § 1983. *Estelle*, 429 U.S. at 104-05. Here, the named Plaintiffs in their motion for preliminary injunction, demand prospective relief that has no bearing upon their condition and that was not considered by the Supreme Court in *Estelle*.

In *Hunt*, the plaintiff alleged that the delay and refusal to address his complaints related to his broken elbow were based on non-medical reasons. 295 F. App'x at 586. Citing cases from other Circuits addressing the delay or denial of medical treatment as supporting claims of deliberate indifference, the Court held that the plaintiff's allegations were sufficient to withstand a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. *Id.* Whether or not Plaintiffs have stated a claim sufficient to survive a motion to dismiss – a motion that Defendants have not filed – is not the question before this Court. Instead, the pertinent question is whether Plaintiff is likely to succeed on the merits such that the extraordinary remedy of preliminary injunctive relief should be entertained. *Estelle* and *Hunt* lend nothing to that analysis.

As a result, Plaintiffs are again left with their singular argument that deviation from the AASLD/IDSA Guidance pertaining to the use of certain contraindications constitutes evidence of deliberate indifference. None of the named Plaintiffs allege that they have or will be denied DAA treatment due to one or more of the contraindications. Plaintiffs also cannot show that they face an excessive risk of some harm by the Department's reliance on the listed contraindications in

determining how or whether to proceed with treatment of HCV positive inmates.

Specifically, Plaintiffs maintain that two particular contraindications – recent alcohol or drug infractions and unstable medical or mental health conditions – have no medical justification and are used improperly by the Department to deny the administration of DAAs. (D.E. 1, ¶¶ 86, 89-90, 92) Notably, however, the AASLD/IDSA Guidance specifically recognizes the value of addressing concomitant substance use disorders along with HCV therapy. (Wilson Aff. ¶¶ 22; Ex. B thereto p. 213) Moreover, Plaintiffs fail to note that, as part of the clearance process to receive DAAs, the Federal Guidelines also require an absence of alcohol and drug related infractions and no uncontrolled or unstable mental health conditions as part of medical clearance for DAA treatment. (Wilson Aff. ¶¶ 23; Ex. C thereto, pp. 33, 37)

Plaintiffs have not presented evidence tending to suggest that they have a high likelihood of success in showing that the Department's contraindications pose an excessive risk of harm to themselves or members of the purported class. This Court should therefore deny any preliminary injunctive relief.

3. The Department's Prioritization of Treatment is not Evidence of Deliberate Indifference.

Although Plaintiffs contend that the Department's prioritization of treatment with DAAs for incarcerated HCV sufferers is some evidence of deliberate indifference, they overlook three key points: 1) the AASLD/IDSA Guidance is not intended to recommend specific courses of treatment; 2) the Guidance expressly recognizes the need to prioritize in certain contexts; and 3) in practice, the application of DAAs requires an individualized patient-specific assessment. As Dr. Wilson noted, the AASLD/IDSA Guidance is not "intended to constitute a specific medical diagnosis, treatment, or recommendation…nor should it be relied on to suggest a course of

treatment for a particular individual." (Wilson Aff. ¶ 16; Ex. B-1 thereto, p. 1) Exclusive reliance upon the AASLD/IDSA Guidance by Plaintiffs ignores this explicit disclaimer. In light of the disclaimer, Plaintiffs' theory that deviation from the AASLD/IDSA Guidance serves as some evidence of deliberate indifference strains credulity.

The AASLD/IDSA Guidance also expressly recognizes the need to prioritize DAA treatment, noting that "in certain settings there remain factors that impact access to medications and the ability to deliver them to patients. In these settings, practitioners may still need to decide which patients should be treated first." (Wilson Aff. ¶ 27; Ex. B thereto, p. 25). As an example, the AASLD/IDSA Guidance recognizes potential barriers to treatment, both inside and outside of the correctional setting. (Wilson Aff. ¶¶ 25-26; Ex. B thereto, pp. 22, 210, 214) Accordingly, Plaintiffs' assertion that prioritizing treatment with DAAs "directly contradicts the AASLD/IDSA [Guidance]" (D.E. 27, p. 18) lacks any merit whatsoever.

For similar reasons, Plaintiffs' contention that the Department's provision of DAA treatment based on an individualized patient-specific assessment is some evidence of deliberate indifference because it deviates from the AASLD/IDSA Guidance also must fail. Notably, the AASLD/IDSA Guidance inherently requires some individualized assessment of patient-specific information before DAA treatment is to be administered. The treatment options provided for in the AASLD/IDSA Guidance are based on genotype, subtype, previous treatment history, degree of liver fibrosis, and other clinical issues. (Wilson Aff. ¶ 15) For this reason, Plaintiffs' attempt to rely on the AASLD/IDSA Guidance in arguing that the Department's prioritization of treatment based on a patient's individual medical needs and history is evidence of deliberate indifference is also not supported.

Finally, Plaintiffs offer no evidence tending to suggest that they or the purported class members are subjected to an excessive risk of harm by the Department's implementation of a treatment protocol that prioritizes care based on patient-specific information. In particular, as Plaintiffs' point out, Kim Caldwell has recently begun receiving DAA treatment in accordance with the Department's current HCV policy.[1] (D.E. 27, p 9)

Plaintiffs also point to two cases that they contend support their position that the Department's prioritization evinces deliberate indifference. These cases are distinguishable because, unlike the Department, the defendants in those cases refused to treat HCV-positive patients until extreme medical complications arose. First, in *Abu-Jamal v. Wetzel*, No. 3:16-CV-2000, 2017 WL 34700, at * 41-42 (M.D. Pa. Jan. 3, 2017), a single inmate challenged a revised HCV protocol that effectively "delayed [treatment] until the inmate faces the imminent prospect of 'catastrophic' rupture and bleeding out of the esophageal vessels." The court noted that "the new protocol completely bars those with chronic hepatitis C but without vast fibrosis or cirrhosis from receiving DAA medications." *Id*. at *44-45. Conversely, the Department does not delay treatment until an inmate shows signs of esophageal varices, and evidence of cirrhosis is not required for DAA treatment. (Wilson Aff. ¶ 36)

Second, in *Hoffer v. Jones*, 290 F. Supp. 3d 1292 (N.D. Fla. 2017), the court noted that under Florida's revised HCV treatment protocol, even patients with F3 or F4 fibrosis scores might not receive DAA treatment. *Id*. at 1303, n. 19. As indicated above, however, the Department's current HCV treatment policy provides for all patients, absent contraindications, with an F2 or

[1] Kim Caldwell can no longer be a class representative under Plaintiff's proposed class definition because he has begun DAA treatment and therefore cannot show a risk of harm based on the Department's screening, monitoring, or treatment protocols.

higher fibrosis score, to be referred to the Hepatology clinic for evaluation for treatment with DAAs. (Wilson Aff. ¶ 38; Ex. D, p. 7)

Plaintiffs have not established that the Department's policy of prioritizing DAA treatment is evidence of deliberate indifference because the AASLD/IDSA Guidance upon which they rely explicitly recognize the appropriateness of prioritization. This Court should therefore deny preliminary injunctive relief on this claim.

B. Other Factors Weigh Against Preliminary Injunction

A plaintiff seeking preliminary injunctive relief also must show that other factors, namely the balance of harm and the public interest, weigh in favor of granting the requested relief. *Winter v. NRDC, Inc.*, 555 U.S. 7, 20 (2008). Plaintiffs overlook these factors and, when taken into account, these factors do not support the issuance of a preliminary injunction.

The preliminary relief requested by Plaintiffs would require an extensive overhaul of the Department's health services operations, including review of logistical considerations of travel and housing assignments for personnel and patients, physical facility capabilities, and human resource capacities. (Wilson Aff. ¶ 8) Accordingly, the balance of harm does not tilt in Plaintiffs' favor. Moreover, Plaintiffs' argument that the public interest would be promoted by awarding the injunctive relief because it would vindicate Plaintiff's constitutional rights (D.E. 27, p. 23) assumes those rights have been violated. For the reasons discussed above, Plaintiffs have not shown that they have a likelihood of success on their deliberate indifference claim and thus are far from establishing a constitutional violated that can be vindicated.

Additionally, the public interest favors allowing state prison administrators the latitude to furnish medical treatment in state prisons without excessive interference from the courts. "[The

Court's] role is not to police the adequacy of prison medical systems." *Dulany v. Carnahan*, 132 F.3d 1234, 1244 (quoting discussion of separation of powers concerns in *Lewis v. Casey*, 518 U.S. 343, 350 (1996)). The public has an interest in allowing state corrections officials to administer medical treatment within prisons in accordance with evidence-based practices. The Department is in the best position to ascertain the medical needs of its patient population and how care should be delivered.

Conclusion

For the reasons stated above, the Court should deny Plaintiffs' motion for preliminary injunction.

This the 5th day of October, 2018.

JOSHUA H. STEIN
Attorney General

/s/ Orlando L. Rodriguez
Orlando L. Rodriguez
Assistant Attorney General
N.C. State Bar No. 43167
orodriguez@ncdoj.gov

s/ Corrine Lusic
Corrine Lusic
Assistant Attorney General
N.C. State Bar No. 50374
clusic@ncdoj.gov

/s/ Joseph Finarelli
Joseph Finarelli
Special Deputy Attorney General
N.C. State Bar No. 26712
jfinarelli@ncdoj.gov

/s/ Ann W. Matthews
Ann W. Matthews
Special Deputy Attorney General
State Bar No. 15971
amatthews@ncdoj.gov

N.C. Department of Justice
P.O. Box 629
Raleigh, North Carolina 27602-0629
Telephone:(919)716-6400
Facsimile:(919)716-6761

CERTIFICATE OF SERVICE

I hereby certify that on this day I electronically filed the foregoing **RESPONSE OF DEFENDANTS TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** with the Clerk of the Court using the CM/ECF system, which will send notification to the following counsel of record:

Michele Luecking-Sunman
Daniel K. Siegel
North Carolina Prisoner Legal Services, Inc.
P.O. Box 25397
Raleigh, NC 27611
(919) 856-2220
mlueckingsunman@ncpls.org
dsiegel@ncpls.org

Christopher A. Brook
Emily E. Seawell
ACLU of North Carolina
P.O. Box 28004
Raleigh, NC 27611
(919) 834-3466
cbrook@acluofnc.org
eseawell@acluofnc.org

This the 5th day of October, 2018.

/s/ Orlando L. Rodriguez
Orlando L. Rodriguez
Assistant Attorney General

CERTIFICATE OF WORD COUNT

The undersigned counsel hereby certifies that the foregoing **RESPONSE OF DEFENDANTS TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION** contains less than 6,250 words. This count includes the body of the reply, headings, and footnotes, but does not include the caption, signature lines, the certificate of service, or this certificate. As such, this reply is complies with Local Rule 7.3(d)(1).

This the 5th day of October, 2018.

/s/ Orlando L. Rodriguez
Orlando L. Rodriguez
Assistant Attorney General